December 6, 2019

etectRx, Inc.
Paul Dryden
Consultant
747 SW 2nd Ave Suite 365T, IMB 24
Gainesville, Florida 32601

Re: K183052
Trade/Device Name: ID-Cap System
Regulation Number: 21 CFR 880.6305
Regulation Name: Ingestible Event Marker
Regulatory Class: Class II
Product Code: OZW
Dated: November 26, 2019
Received: November 27, 2019

Dear Paul Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Jessica Paulsen
Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on last page.

510(k) Number *(if known)*

K183052

Device Name

ID-Cap System

Indications for Use *(Describe)*

The ID-Cap System consists of a wearable reader for ambulatory recording of events signaled by swallowing the ID-Capsule which contains the ID-Tag, an ingestible sensor. The ID-Cap System is intended to log, track, and trend intake times and enables unattended data collection for clinical applications. The ID-Cap System may be used in any instance where quantifiable analysis of ingestion events, including events signaled by the co-incidence with or co-ingestion with the ID-Capsule, is desirable.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

4-December-19

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Proprietary or Trade Name: ID-Cap System

Common/Usual Name: Ingestible event marker

Classification Name: 21 CFR 880.6305
OZW – Ingestible event marker Class II

Predicate Devices: K150494 – Ingestion Event Marker (IEM) Data recorder (Patch)

Device Description

The ID-Cap System is an ingestible event marker. It utilizes an in vivo communications technology that emits a very low power radio frequency (RF) digital message from within the patient after a sensor is ingested and detects the signal using a wearable Reader.

The ID-Cap System is comprised of the ID-Capsule, the ID-Cap Reader, and related software which allows data to be displayed for the patient and clinician.

The ID-Capsule consists of a standard pharmaceutical capsule shell containing the ID-Tag (the ingestible sensor).

The ID-Cap Reader is a wearable device, which receives the message from the ID-Tag, verifies the message as being a valid ingestion event, and forwards the data using the Bluetooth Low Energy (BLE) protocol to data display systems utilized by clinicians and patients.

Indications for Use

The ID-Cap System consists of a wearable reader for ambulatory recording of events signaled by swallowing the ID-Capsule which contains the ID-Tag, an ingestible sensor. The ID-Cap System is intended to log, track, and trend intake times and enables unattended data collection for clinical and research applications. The ID-Cap System may be used in any instance where quantifiable analysis of ingestion events, including events signaled by the co-incidence with or co-ingestion with the ID-Capsule, is desirable.

Comparison of ID-Cap System to Predicate

We present in **Tables 1 – 5** a comparison of the subject device compared to the predicate.

Table 1 – Comparison - High-Level System

	Predicate K150494	Subject Device	Comments
Trade Name	Proteus Digital Health Feedback Device	ID-Cap System	
Classification	Ingestible Event Marker (21 CFR 880.6305)	Ingestible Event Marker (21 CFR 880.6305)	Identical
Product Code	OZW, DXH	OZW	Product code DXH is not relevant for the subject device, since the subject device does not include a telephone electrocardiograph transmitter and receiver.
System Components	Ingestion Event Marker (IEM) Data recorder (Patch) Software	ID-Capsule (with ID-Tag) ID-Cap Reader Software	Similar components. An ingestible sensor, a wearable data recorder, and software
Indications for Use	The Proteus Digital Health Feedback Device consists of a miniaturized, wearable sensor for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), and time-stamped patient logged events, including events signaled by the co-incidence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Proteus Digital Health Feedback Device is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The Proteus Digital Health Feedback Device may be used in any instance where quantifiable	The ID-Cap System consists of a wearable reader for ambulatory recording of events signaled by swallowing the ID-Capsule which contains the ID-Tag, an ingestible sensor. The ID-Cap System is intended to log, track, and trend intake times and enables unattended data collection for clinical applications. The ID-Cap System may be used in any instance where quantifiable analysis of ingestion events, including events signaled by the co-incidence with or co-ingestion with the ID-Capsule, is desirable.	The indications for use of the subject device are a subset of the indications for use of the predicate.

	Predicate K150494	Subject Device	Comments
	analysis of event-associated physiological and behavioral metrics is desirable and enables unattended data collection for clinical and research applications.		
Patient Population	Based on current labeling, clinical study volunteers were 21–85 years old (mean: 44.6 years).	Clinical study participants were 18 – 79 years old (mean 41.9 years), stratified by gender and BMI.	Similar
Environment of Use	Ambulatory use Unattended data collection for clinical and research applications Do not wear during airplane travel Intended for use in specified electromagnetic environment	Ambulatory use Unattended data collection for clinical and research applications Not intended for use on aircraft Intended for use in specified electromagnetic environment	Identical Neither is designed for use in aircraft
Prescription use	Yes	Yes	Identical

Table 2 – Comparison - Technological Characteristics – Ingestible Sensor

	Predicate K150494	**ID-Cap System**	**Comments**
Name	Ingestion Event Marker	ID-Capsule (capsule containing the ID-Tag, an ingestible sensor)	
Ingestible Sensor	Integrated circuit (IC) with attached 5 mm diameter x 300µm semi-rigid insulating skirt disk (excipient skirt)	ID-Tag is a 22.5 mm x 9.5 mm x 60 microns (L x W x H) flexible substrate with printed antenna, attached IC and capacitor	Different physical characteristics of ingestible sensor – Both are ICs mounted on a small, thin substrate.
Basic Technology	Bio-galvanically powered ingestible circuit	Bio-galvanically powered ingestible circuit	Similar
Method of Signal Communication	Volume conduction communication High frequency AC (alternating current)	Very low power digital radio frequency (RF) messages	Different method of signal communication, but fundamentally a low-powered signal
Electrical Power Source	Differential metal contacts (Mg-CuCl) activated by electrolytes in stomach fluid Mineral biogalvanic	Differential metal contacts (Mg-AgCl) activated by electrolytes in stomach fluid Mineral biogalvanic	Similar means of powering but using different metal technology
Activation	When wet in stomach	When wet in stomach	Similar activation
Time to Detect	1.0 minute (mean) in direct observation clinical study	6.4 minutes (mean) for ID-Tag encapsulated in ID-Capsule in direct observation clinical study	The capsule takes ~ 6 minutes to dissolve vs. the predicate which is not encapsulated; however, the duration of detected signal is longer for the subject device.
Duration of Detected Signal	7.29 minutes (mean) in direct observation clinical study	27.9 minutes (mean) from first detection in direct observation clinical study	Subject device has a longer duration of detection
Signaling Control	1 mm x 1 mm x 0.3 mm complementary metal-oxide semiconductor (CMOS) IC	1 mm x 1 mm x 0.3 mm complementary metal-oxide semiconductor (CMOS) IC	Similar
Oral Delivery Vehicle	Ingestible sensor is attached to an inert pharmaceutical excipient tablet	Ingestible sensor is encapsulated in a standard pharmaceutical capsule shell	Similar – Oral delivery vehicles for both are inert and listed in the FDA inactive ingredient database.

	Predicate K150494	ID-Cap System	Comments
Swallowable Size and Weight	Round pill *Size:* 6.5 mm x 2.0 mm *Weight:* 80 mg	Capsule Size and weight below for size 00 gelatin capsule *Size:* Locked length = 23.5 mm Cap diameter = 8.56 mm Body diameter = 8.21 mm *Weight:* 24.3 mg	The subject device is delivered in a standard pharmaceutical capsule shell, while the predicate is a tablet configuration.
Patient-Contacting Material	Tested per ISO 10993-1	Tested per ISO 10993-1	Testing per ISO 10993, and all patient-contacting materials found biocompatible
Data Transmitted from the Sensor	Digital signaling information, including unique ID for the ingestible sensor	Digital signaling information consisting of RF signals with encoded digital data	Similar data transmitted. See row below for unique ID discussion.
Unique ID for Sensor	Each sensor is encoded with a unique ID which is recorded by the patch.	The ID-Tag sends RF messages to the Reader which assigns a unique ingestion event ID number to the ID-Tag messages received.	Unique ID is generated within the Reader vs. pre-assigned to the ingestible sensor. Simultaneous ingestions of multiple ID-Capsules are not recommended with the subject device.
Excretion	Chip excreted via GI tract	ID-Tag excreted via GI tract	Similar Safety demonstrated in clinical studies with post-ingestion X-ray confirmation of non-retention of ID-Tags.
Maximum Number of Ingestions per Day	Do not exceed more than 30 ingestions per day.	No more than five ingestions per day, with a minimum of 90 minutes between ID-Capsule ingestions to ensure that each ID-Tag is appropriately identified and each ingestion event is detected.	Single ingestions with a minimum of 90 minutes between ingestions for the subject device.

Table 3 – Comparison - Technological Characteristics – Data Recorder

	Predicate K150494	**ID-Cap System**	**Comments**
Common name	Proteus Personal Monitor (Patch)	ID-Cap Reader	
Data Recorder Description	Adhesive patch worn on the skin	Pendant hanging from a lanyard worn around the neck	The subject device Reader is not attached to the patient's skin.
Function	Receives, stores, and wirelessly sends ingestion confirmation data to a general computing device	Receives, stores, and wirelessly sends ingestion confirmation data to a general computing device	Similar
Form Factor	Body-worn sensor attached to the skin with an adhesive patch	Pendant hanging in front of the chest from a lanyard placed loosely around the neck	Similar, except predicate is an adhesive patch placed on the patient's skin
Memory and Data Storage	Stores data Ovoid patch 4 MB or 16 MB; Rectangular patch 16 MB	Stores data 8 MB	Similar Storage capacity is adequate for the intended use.
Size	One-Piece Ovoid Patch: 102 mm x 60 mm x 9.8 mm or 102 mm x 60 mm x 6.3 mm Two-Piece Rectangular Patch: 98 mm x 42 mm x 11 mm	97 mm x 47 mm x 23 mm	Similar - Both are small and wearable. The subject device can be easily taken off between ingestions.
Weight	Ovoid Patch 10 g or 11 g Rectangular Patch 16 g	78 g	
Battery Type	Lithium Manganese (LiMn) Coin Cell	Rechargeable Lithium Polymer	Similar - The subject device is a rechargeable unit, whereas the predicate is a one-time use, disposable unit.
Battery Life	Data recording for 5-7 days	Rechargeable battery designed to last at least 36 hours on a full charge; Qi-compliant wireless charger included with Reader	Similar – Battery life is adequate for intended use.
Data Reception	Wireless, skin contact required	Wireless, skin contact not required	Subject device does not require skin contact.

	Predicate K150494	ID-Cap System	Comments
Data Recorded	Time-stamped, patient-logged events, including events signaled by swallowing the Ingestion Event Marker (IEM) accessory Records digital ID and date and time of ingestion confirmation Records heart rate, activity, body angle relative to gravity (body position), temperature, heart rate variability, respiratory rate, and inter-electrode impedance	Time-stamped, patient-logged events, including events signaled by swallowing the ID-Capsule Records assigned ingestion event ID number and date and time of ingestion confirmation No physiological metrics collected Records Reader status and channel communication information	The ingestion event marking is similar. The subject device does not capture physiological metrics.
Device Monitoring	Inter-electrode impedance helps determine proper wearing of patch for detection	Reader messages communicate device status. Accelerometer (motion detection) provides insight into patient use of Reader and whether user is wearing it.	The subject device Reader is less position and placement dependent than the predicate device.
Manual Event Logging	Manually press an event marker button on the Patch *Sensor technology:* patient-activated button *Method:* digital pulse	Not on the ID-Cap Reader, but available in the ID-Cap App	The subject device does not have a manual event logging feature itself; however, the ID-Cap App does.
Data Communication	Wirelessly sends data to a general computing device via Bluetooth	Wirelessly sends data to a general computing device via Bluetooth Low Energy (BLE) protocol	Similar methods
User Interface	Patch button initiates communication to mobile computing device Manual event marker button Indicator light	Single on/off/standby button – once turned on, device is ready for use Tri-color LED indicator light	Similar - Simple user interface
Reusable Components / Disposal	Single-use only	Reusable	The subject device Reader is reusable.

Table 4 – Comparison of Performance Testing

	Predicate K150494	ID-Cap System	Comments
Biocompatibility and Toxicity Testing			
Biocompatibility and Toxicity –Data Recorder (Reader)	Patch is attached to the patient's skin Tested and demonstrated to be biocompatible and non-toxic	Reader has no direct attachment to the patient Tested and demonstrated to be biocompatible and non-toxic	ISO 10993 testing performed includes: cytotoxicity, sensitization, and irritation testing.
Biocompatibility and Toxicity – Ingestible Sensor	Ingestible sensor demonstrated to be biocompatible and non-toxic	Ingestible sensor demonstrated to be biocompatible and non-toxic	ISO 10993 testing performed includes: cytotoxicity, sensitization, irritation, pyrogenicity, implantation, acute systemic toxicity, and subacute systemic toxicity.
Additional biocompatibility testing	Chemical characterization with risk-based toxicity assessment	Chemical characterization with risk-based toxicity assessment	Testing and assessment performed
Electrical Safety, EMC, and Battery Testing			
Electrical Safety	IEC 60601-1	IEC 60601-1:2005 (3rd Edition) IEC 60601-1-11:2015	Tested to applicable standards and passed
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2:2014 (4th Edition and home use levels) JIS T 0601-1-2 (12th Edition 2012)	Tested to applicable standards and passed
Wireless Coexistence Performance	Tested	ANSI C63.27 2017 Wireless Coexistence	Testing performed and acceptable
Spectrum Compatibility and RF Safety	N/A	FCC and Industry Canada Grant of Authorization received – relevant Rules Parts and Radio Systems Specifications	Testing performed and acceptable
Mechanical and Electrical Performance			
Impact Resistance	Passed	IEC 60601-1:2005 (3rd Edition) IEC 60601-1-11:2015	Testing performed and results acceptable
Performance of Antenna Used in IEM	Mechanical strength Residual solvent of disc material Friability Electrical properties of disc	Mechanical strength N/A N/A Electrical properties	Applicable testing performed and results acceptable

	Predicate K150494	ID-Cap System	Comments
Non-Clinical Performance Testing of Ingestible Sensor	Tested for activation time and lifetime after activation	Tested for activation time and lifetime after activation	Applicable testing performed and results acceptable
Signal Reception Performance of Data Recorder	High frequency (HF) and low frequency (LF) signal chain performance tests	Reader bench testing	Applicable testing performed and results acceptable
System Performance Testing	Device performance for event marking in simulated bench testing and clinical testing	Device performance for event marking in simulated bench testing and clinical testing	Similar
Proper Excretion of Device	Animal testing	Post-ingestion X-rays in clinical studies	Human testing performed with X-ray confirmation of non-retention for the subject device.
Shelf-Life	Testing referenced in labeling	Shelf-life testing performed for ID-Capsules, and shelf-life/aging analysis performed for Readers.	Applicable testing performed and results acceptable
Human Factors and Usability Evaluation			
Human Factors/Usability	Testing performed	Testing performed with two user groups: patient users and clinician users	Human factors/usability testing performed and results acceptable

Table 5 – Comparison of Clinical Performance

	Predicate K150494	ID-Cap System	Comments
Clinical Studies of Safety and Performance – Key Measures			
Positive Detection Accuracy (PDA)	97.2% (95% CI) cumulative average	95.0%	Similar PDA
Negative Detection Accuracy (NDA)	100% (95% CI) cumulative average	100% (95% CI)	Similar NDA
Maximum daily ingestions in clinical studies	34 IEMs	5 ID-Capsules	Subject device is not designed for multiple ingestible sensor ingestions simultaneously; therefore, fewer total daily ingestions are possible.
Unanticipated adverse device effects	None	None	Similar
Severe adverse events related to or possibly related to the System	None	None	Similar
Discontinuations due to AEs	2.8% of subjects discontinued due to skin irritation	None	Subject device does not have direct skin contact; thus, this risk is mitigated.
Ingestible sensor AEs	5.7% of subjects (overall non-serious AEs – 92% mild and 8% moderate in severity) 0% of ingestions	10.2% of subjects (100% mild in severity) in pooled safety analysis Incidence of at least one related AE is 0.6% of ingestions	Similar with respect to incidence and severity of adverse events reported with use of the device in clinical studies.
Data recorder AEs	17.7% of subjects reported localized skin irritation and inflammation with patch	None	Subject device design mitigates this risk.

Discussion of the Comparison and Differences

As presented in **Tables 2 - 5,** we have compared the etectRx ID-Cap System ("ID-Cap System") to the predicate, Proteus Digital Health Feedback Device ("Proteus" cleared under K150494) for equivalence of:

Indications, Patient Population and Environment of Use – The ID-Cap System is seeking similar indications for use as a device which is intended to log, track, and trend intake times and enables unattended data collection for clinical and research applications. It may be used in any instance where quantifiable analysis of ingestion events, including events signaled by the co-incidence with or co-ingestion with the ingestible sensor, is desirable.

The patient population and environment of use are similar.

Discussion – The indications for use of the subject device are a subset of the indications for use of the predicate. These differences do not raise new or different risk concerns than the predicate; thus, they are substantially equivalent.

Prescription-Use Only – Both devices are prescription-use only.

Discussion – There is no difference in the type of device as a prescription device; thus, they are substantially equivalent.

Design, Technology and Principle of Operation – The fundamental design, technology, and principle of operation of a bio-galvanically powered ingestible circuit that, when activated by stomach fluid, sends a wireless signal to a data recorder is similar between the subject device and predicate.

The subject device generates a unique ID for the ingestion event when the Reader detects the first signal from the ingested sensor, whereas the predicate sensor is pre-assigned a unique ID that is then transmitted to the data recorder (i.e., patch).

Discussion – The subject ID-Capsule which encapsulates the ID-Tag is a standard pharmaceutical capsule shell which dissolves, allowing the ID-Tag to be activated. The time to activation is longer than the predicate as the capsule must first dissolve, but the time available to detect the output signal from the ID-Tag is significantly longer.

The subject device Reader receives the RF signal with no requirement for direct skin contact, while the predicate requires the data recorder (i.e., patch) to be attached to a specific location over the stomach and adhere properly to the patient's skin in order to receive the signal via conduction.

The information transmitted for the subject device relates only to the ingestion event and Reader status. The subject device does not collect, send, or track physiological metrics like the predicate.

The difference of how the unique ID is provided still results in each ingestion event being recorded and tracked under a unique ID.

These differences do not raise different risk concerns than the predicate; thus, they are substantially equivalent.

Performance –

Non-Clinical Testing Summary -

Biocompatibility – In following the Special Controls, ISO 10993-1 testing was performed as appropriate for the respective patient-contacting materials in the ingestible sensor and the data recorder.

Discussion – The test results demonstrated that the patient-contacting materials were biocompatible.

Bench Testing
The subject device has been tested for performance and compliance as it relates to electrical safety, EMC, wireless coexistence, shelf-life, mechanical performance, electrical performance, ingestible sensor performance, Reader detection performance, and system performance to ensure that all requirements have been met.

Discussion – The subject device met its performance requirements. Any differences did not raise new or different concerns about safety or effectiveness, and, thus, the subject device can be considered substantially equivalent to the predicate.

Human Factors/Usability – As required under the Special Controls, we performed Human Factors / Usability testing. We identified the applicable user groups and conducted a summative usability validation study. The results supported the design, function, appropriate use, and performance of the subject device for the intended use population.

Clinical Testing Summary -
The clinical trials performed demonstrates that the ID-Cap System does not raise different questions of safety and effectiveness. These clinical trials included evaluations of the following parameters:

- Positive Detection Accuracy (PDA)
- Negative Detection Accuracy (NDA)
- Effect of gender and BMI on PDA
- Time to detection of ingestion
- Duration of detected signal
- Time to phone receipt and time to server receipt following ingestion of the ID-Capsule
- Adverse events
- Proper excretion of ID-Tags as evidenced by post-ingestion X-rays showing non-retention ofID-Tags

Substantial Equivalence Conclusion

The ID-Cap System is substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, specifications / performance, and clinical evaluations.

The differences, as detailed above, do not raise different risks of safety and effectiveness. Thus, the subject device can be considered substantially equivalent to the predicate device.